

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY


(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 24 MAY 2006

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Applicant's or agent's file reference 2002034-WO		FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/EP2005/050328		International filing date (day/month/year) 26.01.2005	Priority date (day/month/year) 27.01.2004	
International Patent Classification (IPC) or national classification and IPC INV. A61F13/02 C09J7/02				
Applicant COLOPLAST AS et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 3 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 05.09.2005		Date of completion of this report 22.05.2006		
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized officer Schlicke, B Telephone No. +31 70 340-1013		



**INTERNATIONAL PRELIMINARY REPORT
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International application No.
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on
- ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-39 as originally filed

Claims, Numbers

1-21 received on 05.09.2005 with letter of 01.09.2005

Drawings, Sheets

1/27-27/27 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has, within the applicable time limit:
- ☐ restricted the claims.
 - ☒ paid additional fees.
 - ☐ paid additional fees under protest and, where applicable, the protest fee.
 - ☐ paid additional fees under protest but the applicable protest fee was not paid.
 - ☐ neither restricted the claims nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☒ complied with.
 - ☐ not complied with for the following reasons:
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos. .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

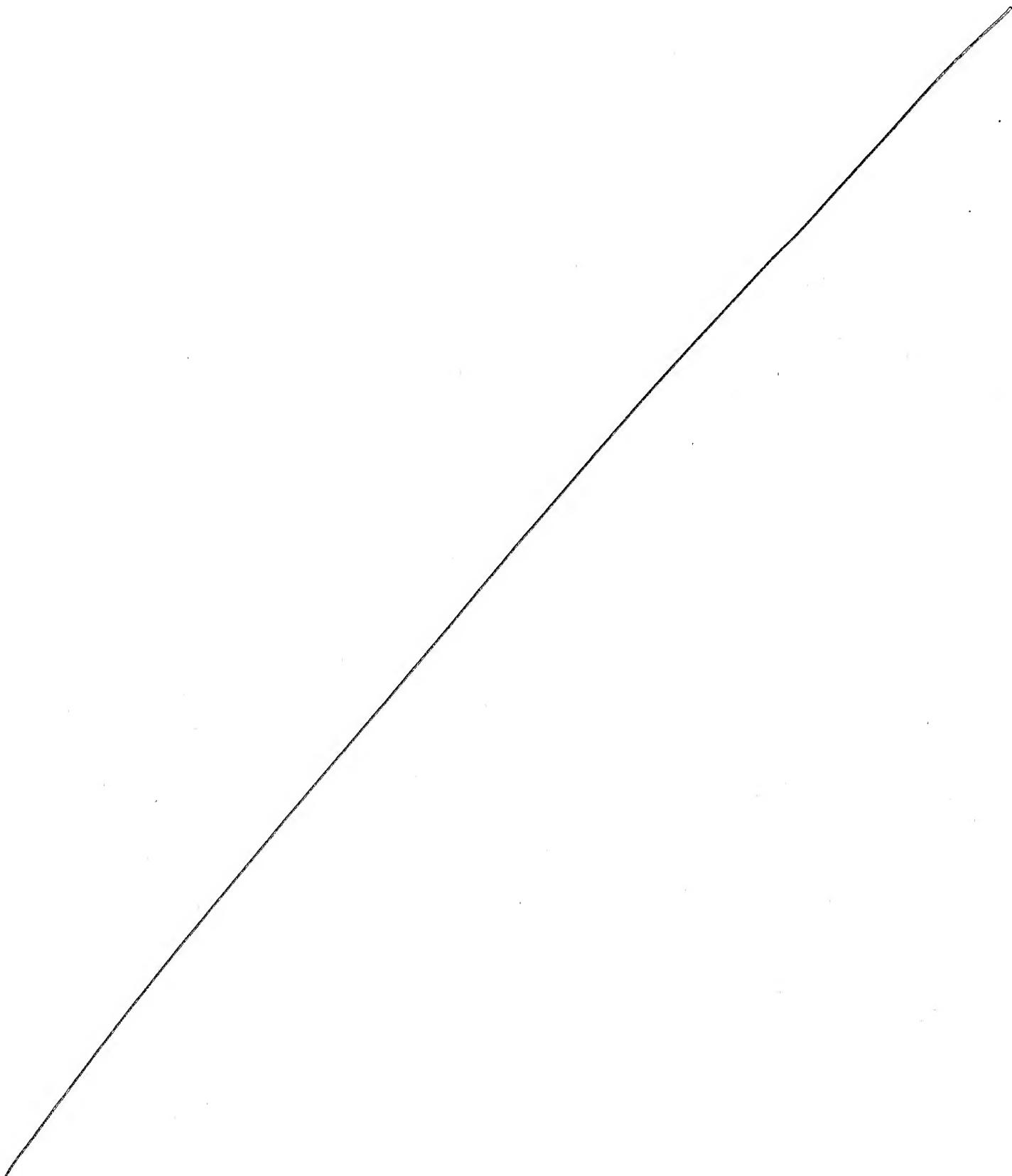
Novelty (N)	Yes: Claims	1-21
	No: Claims	
Inventive step (IS)	Yes: Claims	1-21
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

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Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1 The present application is directed to an adhesive absorbing element comprising hydrocolloids in a tacky elastomeric matrix wherein at least a part of a first facade of the element comprises grottos of at least 5 μm in diameter and the average size of the grottos is less than 300 μm .

2 Reference is made to the following documents:

D1: EP-A-0 806 210 (HOLLISTER INCORPORATED) 12 November 1997

D2: WO 94/15562 A (COLOPLAST A/S) 21 July 1994

D3: US-B1-6 566 575 (STICKELS STEVEN C ET AL) 20 May 2003

3 Document D1 discloses (claims 1,10; col. 3, lines 55-57; fig. 1,4) an adhesive absorbing element comprising hydrocolloids in a tacky elastomeric matrix. The bodyside surface of said absorbing element is embossed to provide a pattern of discrete, non-connecting depressions ("grottos") with a width of *more than 500 μm* .

Hence, the subject-matter of independent claim 1 is novel in view of this teaching (Article 33(2) PCT).

4 Document D2 discloses (fig. 3,3a,3',3a'; page 23, line 34 - page 24, line 30; page 25, line 25 - page 26, line 16; page 9, line 32 - page 10, line 10; page 15, lines 9-12) a flat skin plate, said device comprising a first hydrocolloid containing elastomeric adhesive matrix material and a second adhesive material forming circular islands ("grottos") of *more than 500 μm* diameter in the first material. The two adhesives materials have different properties.

Hence, the subject-matter of independent claim 1 is novel in view of this teaching (Article 33(2) PCT).

5 Document D3 discloses (claims 1,5,7; fig. 1; col. 14, line 55 - col. 15, line 19) an

absorbing dressing comprising hydrocolloids in an elastomeric matrix. The surface of said absorbing element comprises pattern elements ("grottos") with a width of more than 100 μm .

Although the wound dressings disclosed in D3 may contain an additional adhesive layer, the absorbent element as such is not reported to show any kind of adhesive properties.

Hence, the subject-matter of independent claim 1 appears to be novel in view of this teaching (Article 33(2) PCT).

- 6 Both, D1 and D3 are directed to absorbing elements and may therefore be considered as representing the closest prior art.

The subject-matter of present claim 1 differs from these known absorbing elements in the considerably smaller size of the grottos.

Since no technical effect resulting from this distinguishing has been shown, the objective problem to be solved may only be regarded as to provide a further absorbing element.

The depressions in the absorbing elements of D1 and D3 serve to reduce the extend of skin surface contact with the absorbent surface area (col. 1, lines 19-25 in D1; abstract in D3). Since this positive effect would diminish with decreasing size of the grottos, the teachings (alone or in combination) prevent the skilled person from arriving at the subject-matter of present claim 1.

Consequently, the present application is considered as involving an inventive step (Article 33(3) PCT).

- 7 None of the available prior art documents alone or in combination with another document suggests a method of producing absorbing elements by heat treatment of selected surface parts as defined in present claim 14. The subject-matter of said claim is therefore novel and appears to involve an inventive step (Article 33(3) PCT).

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- 8 Claims 2-13 and 15-21 are dependent on claim 1 and 14 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

An absorbing article with zones of different surface properties, PCT/EP2005/050328

Coloplast A/S, 2002034 WO

30 August 2005

5 CLAIMS

1. An absorbing element having adhesive properties comprising hydrocolloids in an elastomeric matrix wherein at least a part of a first facade of the absorbing element comprises grottos of at least 5 μ m in diameter and the average size of the grottos is less than 300 μ m.
- 10 2. An absorbing element according to any of the preceding claims, wherein the grottos are obtained by heat treatment of the absorbing element.
3. An absorbing element according to any of the preceding claims, wherein the grottos are obtained by heating the absorbing element.
- 15 4. An absorbing element according to any of the preceding claims, wherein the absorbing element is a pressure sensitive adhesive.
5. An absorbing element according to any of the preceding claims, wherein the first facade is adapted for releasable adhesion to skin.
- 20 6. An absorbing element according to any of the preceding claims, wherein the hydrocolloids are selected from the group consisting of naturally occurring hydrocolloids such as guar gum, locust bean gum, pectin, alginates, gelatine, xanthan or karaya gum; semisynthetic hydrocolloids such as cellulose derivatives, e.g. salts of carboxymethylcellulose, methylcellulose and hydroxypropylmethylcellulose, sodium starch glycollate; microcolloids; and synthetic hydrocolloids such as polyvinyl pyrrolidone, polyvinyl alcohol, polyethylene glycol or certain polyacrylates.
- 25 7. An absorbing element according to any of the preceding claims, wherein the elastomeric matrix is self adhesive.
8. An absorbing element according to any of the preceding claims, wherein the elastomeric matrix is a rubbery elastomeric base.
- 30 9. An absorbing element according to any of the preceding claims, wherein the elastomeric matrix is of material that do not flow at room temperature.

10. An absorbing element according to any of the preceding claims, wherein the grottos are obtained by heat treatment of the part of the first facade of the absorbing element with electromagnetic radiation with a wavelength of more than 400nm.
- 5 11. An absorbing element according to any of the preceding claims, wherein the heat treatment comprises irradiation of the first facade with an infrared laser.
12. An absorbing element according to any of the preceding claims, wherein the average size of the grottos is less than 200µm, such as less than 100µm.
- 10 13. An adhesive element as claimed in any of the preceding claims, said adhesive element being adapted to form part of a medical device, such as an ostomy body-side member or a wound care dressing.
14. A method of producing an adhesive element comprising an adhesive layer, the adhesive layer comprising at least a first zone having a first surface associated with a first set of surface properties and at least one second zone having a second surface constituting at least a part of the adhesive surface of the adhesive element, the second surface being associated with a second set of surface properties differing from the first set of surface properties, wherein material as present in the second surface is obtainable by a heat treatment of material in the first surface, said material comprising a pressure sensitive adhesive composition, said method comprising the steps of:
- 15
- 20
- providing an adhesive element comprising an adhesive layer,
 - selecting a heat source,
 - locating the adhesive layer and the heat source in a relationship enabling a heat treatment of the second surface of the adhesive layer, and
 - heat treating the second surface with the selected heat source for a sufficient time for
- 25 obtaining the second set of properties.
15. A method as claimed in claim 14, wherein the heat treatment comprises contact heating or convection heating.
16. A method as claimed in any of claims 14-15, wherein the heat treatment comprises irradiation of the second surface with electromagnetic radiation with a wavelength above 400nm.
- 30
17. A method as claimed in claim 16, wherein the irradiation comprises irradiation with a laser or a polychromatic lamp.

18. A method as claimed in any of claims 14-17, wherein the heat treatment is performed using a mask for protecting parts of the surface to be less treated, said mask covering a part of the surface layer.
- 5 19. A method as claimed in any of claims 14-18, wherein the heat treatment is performed progressively such that the heat treatment of a first portion of the second zone of the adhesive layer is delayed compared to the heat treatment of second portion of the second zone of the adhesive layer.
20. A method as claimed in any of claims 14-19, wherein the heat treatment comprises writing a pattern on the surface of the adhesive layer with an infrared laser.
- 10 21. A method as claimed in any of claims 14-20, wherein the heat treatment is performed through a liner in contact with the adhesive layer.